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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BARTON, JEFFREY THOMAS	
ART UNIT	**PAPER NUMBER**
1753	

DATE MAILED: 04/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/907,001	YAGER ET AL.	
	Examiner	Art Unit	
	Jeffrey T. Barton	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-26,28-31 and 34-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-26,28-31 and 34-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7 February 2006 has been entered.

Response to Amendment

2. The amendment filed on 7 February 2006 does not place the application in condition for allowance.

Status of Objections and Rejections Pending Since the Office Action of 3 August 2005

3. All previous objections and rejections are withdrawn due to Applicant's amendment.

Claim Objections

4. Claim 30 is objected to because in line 2 it refers to "each separation channel", although no separation channels were recited previously. Appropriate correction is

required. It appears that "channels" should be recited in claims 30 and 31, as opposed to "separation channels".

5. Claim 28 is objected to because in line 2 it refers to "the plurality of anodes and the plurality of cathodes", with no antecedent basis for these pluralities.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 24, 28, 29, 38, and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Hollis et al.

Hollis et al discloses the formation of a device having a channel and plurality of electrodes as claimed formed in the channel (Figures 18 and 19; Column 14, lines 50-52 describes formation of the channel and array on a single chip) They disclose formation of the channels from a mold that is the inverse of the desired pattern (Column 15, lines 7-14), using a technique (Thermocompression molding) that inherently uses polymeric materials, forming the channels in a polymeric substrate, and fusing the substrate to a solid support (e.g. layer 344). This method reads on steps a-c as claimed. The formation of electrodes 12' of spatially-dispersed array 10' reads on the

limitations of step (d). Formation of such arrays is described with reference to Figures 1-6.

Regarding claims 28 and 29, the electrodes of array 12' are disposed such that they can generate field in numerous non-parallel directions.

Regarding claims 38 and 39, Hollis et al disclose numerous electrodes disposed in the central region as claimed. (Figure 1; Column 5, lines 35-40)

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 24, 28, 29, 38, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hollis et al in view of either Ekström et al or Kaltenbach et al. This rejection is based on an alternative reading of Hollis et al, where the thermocompression molding step is not considered to inherently require polymer.

Hollis et al discloses a method as described above in paragraph 7.

Hollis et al do not explicitly disclose forming their device on a polymer substrate.

Ekström et al disclose a method of preparing a microfluidic chip comprising the steps of: lithographically forming a mold that is a reverse of the desired channel structures (Column 4, line 61 - Column 5, line 30); casting or imprinting the channels in a polymeric substrate as a negative impression of the mold (Column 5, lines 31-57); and fusing the polymeric substrate to a solid support (Column 6, lines 38-55)

Kaltenbach et al disclose a method of preparing a microfluidic chip comprising the steps of: lithographically forming a mold that is a reverse of the desired channel structures (Column 7, line 55 - Column 8, line 30); casting the channels in a polymeric

substrate as a negative impression of the mold (Column 8, lines 16-30); and fusing the polymeric substrate to a solid support (Column 10, lines 49-55)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Hollis et al by forming the channel in a polymer substrate, as taught by either Ekström et al or Kaltenbach et al, because it would significantly reduce production costs relative to other materials, and simplify mass production of the devices. Additionally, Hollis et al disclose forming the devices on dielectric material (Column 14, lines 50-52), and a skilled artisan would have recognized that polymers are suitable dielectric substrates for microfluidic devices. (See Kaltenbach et al and Ekström et al)

12. Claims 24, 26 28, 29, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Renfrew et al in view of Manis et al and Arayama. (English Abstract of JP 03-167468; Figures from Japanese Document - translation will be prepared)

Renfrew et al disclose a microelectrophoresis chip (Figures 1-3) having a plurality of parallel slab gels, which read on the broad recitation of "channels", defined by lane markers shown in Figure 3. (Column 3, lines 4-11)

Renfrew et al do not explicitly disclose the method of forming the chip, teaching only that a spacer is used, with the two plates as shown. They also do not explicitly disclose providing the plurality of electrodes within each channel as claimed.

Manis et al teach forming plates for an electrophoresis cassette using injection molding (Column 4, lines 3-10), which inherently involves forming a mold that is the

reverse of the desired pattern and casting the desired pattern as a negative impression of the mold. One plate is molded to have raised areas to provide the opening for the slab gel, eliminating the need for a separate spacer. (Column 4, lines 20-23) The two plates are fused together to form the cassette. (Column 4, lines 18-28)

Arayama et al teach the provision of a matrix of electrodes in a plate of a gel electrophoresis cassette, in order to provide free control of the migration of a sample. The formation of the array meets the limitations of step (d) as claimed. (English Abstract; Figures)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Renfrew et al by forming it by injection molding of two plates, one of which incorporates raised portions that replace the spacer, as taught by Manis et al, because it would facilitate mass production of the cassette plates at low cost, and simplify assembly of the cassettes by reducing the number of parts that are assembled. (i.e. two instead of three) Given the micron-scale dimensions of the lane dividers of Renfrew et al, use of lithography to form the mold would have been obvious to one of ordinary skill, as it was well known to provide sufficient control of feature size and etch depth.

It would also have been obvious to one having ordinary skill in the art at the time the invention was made to further modify the device of Renfrew et al by providing an array of electrodes on one of the plates in each slab gel section (i.e. each channel), as taught by Arayama et al, because it would provide vastly increased control of the separation, allowing migration of different components in different directions. One

having ordinary skill in the art would have recognized the usefulness of this in simplifying the separation of extremely complex mixtures.

13. Claims 25 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Renfrew et al, Manis et al, and Arayama as applied to claims 24 and 29 above, and further in view of Soane. (US 5,071,531)

Renfrew et al, Manis et al, and Arayama teach a combined method as described above in addressing claims 24 and 29. Renfrew et al disclose channel depths as low as 25 microns. (Column 4, line 64 - Column 5, line 2) They teach the difficulties of using smaller gaps (Column 5, lines 2-8), but do not teach that they cannot be used, thus the reference does not teach away from such modification.

None among Renfrew et al, Manis et al, and Arayama explicitly teach gel thickness (i.e. channel depth in the cassette of Renfrew et al) of 1 to 10 microns.

Soane teaches using a slab gel thickness of ten microns. (Figure 1, Column 4, lines 18-33)

It would have been obvious to one having ordinary skill in the art to further modify the method of Renfrew et al by choosing a gel thickness of 10 microns, as taught by Soane, because a skilled artisan would have been able to choose any suitable gel thickness, based on sample size or other considerations particular to a given analysis. Detection of small-volume samples would clearly be simpler in thinner gels. (e.g. 10 microns or thinner) Furthermore, in *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 830, 225 USPQ 232 (1984), the

Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

14. Claims 25 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hollis et al in view of Soane et al. (US 5,126,022)

Hollis et al disclose methods as described above.

Hollis et al do not disclose any particular channel depth within their system, although use of the terms "microchannel" and "microfluidic" suggest micrometer-scale channel dimensions. (Column 14, lines 34-43)

Soane et al teach microchannel systems 5-25 micrometers in depth. (Column 4, lines 43-47)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Hollis et al by specifically using a channel depth of 10 microns or less, as taught by Soane et al, because a skilled artisan would have realized that any channel depth that allows movement of analytes over the electrode array would have been suitable in the device of Hollis et al, and that reduced dimensions (i.e. <10 microns) would have been advantageous in allowing smaller sample volumes and/or avoiding excessive dilution of the samples. This would have been reasonably expected to provide greater device sensitivity.

Additionally, in *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. Such appears to be the case here.

15. Claims 25 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hollis et al and either Ekström et al or Kaltenbach et al as applied to claims 24 and 29 above, and further in view of Soane et al. (US 5,126,022)

The reasoning for this rejection parallels that given above in paragraphs 11 and 14.

16. Claims 26 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hollis et al in view of Sethi et al.

Hollis et al discloses methods as described above. In addition, Soane et al suggest plural elements being encompassed by their disclosure. (Column 4, lines 20-23)

Hollis et al do not explicitly disclose the preparation of plural channels in a substrate.

Sethi et al disclose lithographic preparation of several analysis channels in a single substrate. (Figure 11)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Hollis et al by fabricating plural analysis channels on the substrate, as taught by Sethi et al, because the complexity of the analysis problems that are proposed to be solved by Hollis et al (Column 16, lines 43-64) would have suggested to any skilled artisan that highly parallel analyses would lead to greater sample throughput and increased efficiency. Preparation of numerous analysis channels on a single substrate, as taught by Sethi et al, would have been an obvious way of achieving this aim.

17. Claims 34 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Renfrew et al, Manis et al, and Arayama as applied to claims 24 and 29 above, and further in view of Jinno et al and Ross et al.

Renfrew et al, Manis et al, and Arayama disclose a combined method as described above in addressing claims 24 and 29. Renfrew et al disclose only a generic gel throughout their specification, with no apparent preference for a particular gel.

None among Renfrew et al, Manis et al, and Arayama explicitly disclose using a separation medium comprising water-soluble fullerenes.

Jinno et al disclose the use of buckminsterfullerene (C_{60}) as a chromatographic stationary phase having unique selectivity for the analyzed compounds. (Abstract, Introduction section)

Ross et al disclose that fullerenes of the formula C_n have a degree of water-solubility. (Abstract)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify the method of Renfrew et al by replacing their gel with a medium comprising fullerenes, as taught by Jinno et al, because Jinno et al teach that they have unique selectivity that would be useful in certain separations, and the silence of Renfrew et al suggests that a skilled artisan could select a gel that is suitable for a given separation. Ross et al teach that fullerenes such as those disclosed by Jinno et al have some solubility in water, which therefore meets the claim limitations.

18. Claims 35 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Renfrew et al, Manis et al, and Arayama as applied to claims 24 and 29 above, and further in view of Tanaka et al and Newkome et al.

Renfrew et al, Manis et al, and Arayama disclose a combined method as described above in addressing claims 24 and 29. Renfrew et al disclose only a generic gel throughout their specification, with no apparent preference for a particular gel.

None among Renfrew et al, Manis et al, and Arayama explicitly disclose using a separation medium comprising self-assembling dendrimers.

Tanaka et al disclose using dendrimers as carriers in an electrophoretic separation, in which the separation was influenced by differential binding of the analytes to the dendrimers and dendrimer size. (Abstract, Figures 1 and 2) The size and binding effects show the dendrimers acting as obstacles to analyte migration.

Newkome et al disclose the preparation of self-assembling dendrimers. (Abstract, Experimental section)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify the method of Renfrew et al by replacing the separation medium with a medium comprising dendrimers, as taught by Tanaka et al, because Tanaka et al teach that dendrimers work well as an alternative to surfactants and their use results in different selectivity that would be useful in certain separations (Page 959-960), and the silence of Renfrew et al suggests that a skilled artisan could select a gel that is suitable for a given separation. Additionally, it would have been obvious to use self-assembling dendrimers, the preparation of which was taught by Newkome et al, because it would simplify dendrimer synthesis, and they would be reasonably expected to provide similar benefits to those disclosed by Tanaka et al.

Response to Arguments

19. Applicant's arguments submitted 7 February 2006 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Jeffrey Barton, whose telephone number is (571) 272-1307. The examiner can normally be reached Monday-Friday from 9:00 am – 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached at (571) 272-1342. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

JTB
13 April 2006

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